Nebraska Nanomedicine Production Plant

The Nebraska Nanomedicine Production Plant (NNPP) is the culmination of the efforts of the founders Ram I. Mahato, Ph.D. and Howard E. Gendelman, M.D.

Dr. Mahato, professor and chair of the department of pharmaceutical sciences, UNMC College of Pharmacy, and Dr. Gendelman, professor and chair, department of pharmacology and experimental neuroscience, UNMC College of Medicine, identified the limitation of nanomedicine research - translating bench research to the clinic.

The mission of the NNPP is to design and produce nanoformulated drugs and peptides for human use in order to improve delivery, efficacy and reduce toxicity of infectious, degenerative, immune and cancerous diseases.

Dr. Mahato said, “Without the NNPP, the College of Pharmacy will not have the platform needed to scale-up its nanomedicines for clinical trials.”

The NNPP is housed in the Nebraska Medicine and UNMC jointly operated Biologics Production Facility. The production plant is centered on the creation of marketable products. Development begins in the pre-production laboratory that provides pharmaceutical-based research projects and bench-scale production of nanomaterials using scalable, FDA (Food and Drug Administration)-

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Nebraska Neuroscience Alliance

In 2011, the Nebraska Neuroscience Alliance was formed to drive clinical scientific advancements in neuroscience here at the University of Nebraska Medical Center.

A permanent Nebraska Neuroscience Alliance (NNA) endowment was established at the University of Nebraska Foundation. This endowment would put the NNA in a position to fund pilot studies at the bench and more importantly in the clinic.

A lot has happened since 2011. First, Matt Rizzo, M.D., was named chair of the department of Neurological Sciences and co-director of the NNA. He brings a wealth of knowledge in interdisciplinary program development.

Next, supporters often wonder what happens to the dollars donated to a fund. The NNA is pleased to announce that the first dollars from the endowment have been used for Parkinson’s disease research and a phase 1 clinical trial here at

see Clinical Trial pg 5
Dear Friends and Colleagues,

2014 has brought many changes to the University of Nebraska Medical Center and our department of pharmacology and experimental neuroscience.

UNMC partnered with The Nebraska Medical Center and now is Nebraska Medicine - a sign of unity in our work force so together we will achieve breakthroughs for life through cutting-edge research, world-class patient care and premier education. Our new chancellor, Jeffrey P. Gold, M.D., is a leader in this effort.

Our laboratories in Swanson Hall are now gone, making room for the Fred & Pamela Buffett Cancer Center. Currently, the majority of our research is conducted in the Durham Research Center towers on the west edge of the medical center campus.

The department, in collaboration with other UNMC departments, is seeing success in translational research with the first of its kind Nebraska Nanomedicine Production Plant. Many new products from sun-screens to anti-HIV medicines will be manufactured in the Biologics Production Facility located here on the Nebraska Medicine/UNMC campus.

Our education of graduate students continues to grow with 43 students enrolled in 2014-15. In 2013-2014, department faculty members taught over 330 lecture hours to graduate and professional students.

We are surrounded by faculty whose performances continue to gain local, national and international attention and awards for innovation, teaching and research.

Our extramural, industry and private research funding has brought our department into the top 10% of all pharmacology departments in the USA.

We began our first phase I clinical trial in Parkinson’s disease with palpable excitement in bringing laboratory inventions to the patient bedside.

All of the above would not be possible without the support of the university, our collaborators, various funding resources, but most of all you.

Thank you for your support. We look to our future and our mission with excitement.

Howard E. Gendelman, M.D.
Chair
Department of Pharmacology and Experimental Neuroscience
University of Nebraska Medical Center
The annual Skate-A-Thon for Parkinson’s disease was held at UNMC’s ice rink on January 10-11, 2014.

The PENguins from 2013 morphed into M & M’s - Movement & Medicine - and slipped around the ice to raise awareness and funds for Parkinson’s disease.

As much fun as this 24-hour event was, this year was bittersweet. Colleen Wuebben, the driving force behind the event, passed away in 2013. Colleen, diagnosed with Parkinson’s in 2005 at the age of 52, and her family started the event in 2008 by flooding their backyard.

The past four events, held at UNMC, have raised over $125,000 for basic science Parkinson’s research at UNMC and the PHD Program (Parkinson’s Health Development), a non-profit, local program that offers affordable exercises and activities to improve quality of life for persons with Parkinson’s.

Join the M & M’s at the fifth annual Skate-A-Thon at UNMC’s ice rink located east of 42nd Street, about halfway between Dewey Avenue and Emile Street.

Team M & M

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Department faculty, Dr. Howard E. Gendelman and Dr. Tony Wilson, along with post-doctoral fellow, Dr. Kelly Stauch, have each received research awards from the Skate-A-Thon.

Dr. Gendelman has used his award to support the Parkinson’s disease Phase 1 Clinical Trial (See Nebraska Neuroscience Alliance article, page 1.)

Dr. Wilson’s award has supported magnetoencephalography (MEG), a method of mapping human brain activity. Patients in the study completed non-invasive MEG scans while they performed movement tasks involving their hands. Researchers are hopeful that the MEG will become a good diagnostic tool for identifying Parkinson’s disease and understanding how the disease modulates brain activity.

Dr. Stauch is building a comprehensive and publicly available human mitochondria reference database. This will allow proteomic screening in order to provide evidence for novel avenues of treatment.

For more information on the Skate-A-Thon, contact UNMC Public Relations 402.559.4353.
The NNPP is an essential resource for Nebraska, advancing promising nanoformulations from preclinical studies to human clinical trials.”

Joseph A. Vetro, Ph.D., Director, NNPP

Production Plant (continued from pg 1)

compliant equipment and facilities. All products will be under careful Good Laboratory and Manufacturing Practices.

Joseph A. Vetro, Ph.D., director of the NNPP, is actively involved in developing polymer-based nanoformulations to improve cancer therapy as well as biodegradable nanoparticles. His role is to coordinate the logistics to produce nanoformulations at pilot-scale levels according to the FDA regulations. Dr. Vetro said, “The NNPP is an essential resource for Nebraska, advancing promising nanoformulations from preclinical studies to human clinical trials.”

JoEllyn McMillan, Ph.D., joins Dr. Vetro as associate director of the NNPP and as the pre-production laboratory chief. Dr. McMillan is an experienced toxicologist with over a decade of laboratory, drug detection and quality control experience.

The immediate goal of the NNPP is to accelerate bench to bedside product development of nanoformulations slated for use in phase I and II clinical trials. Currently, two UNMC backed nanoformulation companies will use the production plant.

ProTransit Nanotherapy, LLC, developers of protein-loaded biodegradable nanospheres, is working on a range of spinal cord and traumatic brain injury therapeutics, strokes, as well as skincare and cosmetics. Gary Madsen, Ph.D., is president and CEO of ProTransit Nanotherapy.

The UNMC NanoART program, under the direction of Dr. Gendelman, fills a void in current HIV/AIDS treatment. The program works towards manufacturing and characterizing stable nanosuspension dosages of long-acting antiretroviral therapy.

Before scale-up production can begin, a pre-production laboratory was set up in conjunction with the Center for Drug Delivery and Nanomedicine. This facility serves as a resource for optimizing the production, purification, lyophilization and characterization of nanoformulations selected for preclinical toxicology studies.

The NNPP will be able to partner with the National Institutes of Health and large pharmaceutical collaborators to create an amazing resource in the heart of the country.

For more information on the Nebraska Nanomedicine Production Plant or Pre-Preproduction laboratory, contact

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Article adapted from the Nebraska Nanomedicine Production Plant brochure, UNMC 2014.
Alumni

Graduate students go on to excel in research, health care and industry.

Congratulations to...

**Awards**

- **Keshore Bidasee, Ph.D.**
  - Most Promising New Invention, UNeMed, 2013
- **Howard S. Fox, M.D., Ph.D.**
  - UNMC Scientist Laureate, 2014
- **Howard E. Gendelman, M.D.**
  - Innovator of the Year, 2013
  - Outstanding Mentor of Graduate Students, 2014
- **Tomomi Kiyota, Ph.D.**
  - Shoemaker Award for Neurodegenerative Research, 2014
- **David McMillan, Ph.D.**
  - UNMC Pioneering Women in Medicine, 2013
- **Philip Purnell, Ph.D.**
  - University of Nebraska Presidential Graduate Fellow, 2014-15
- **Tony Wilson, Ph.D.**
  - Joseph P. Gilmore Distinguished Basic Scientist Award, 2014
- **Jialin Zheng, M.D.**
  - Director, Asia Pacific Rim Development Program
  - Ten-year anniversary

**Clinical Trial (continued from pg 1)**

UNMC. This trial (NCT01882010) is testing the safety and potential efficacy of an immune regulatory drug. Yes, we moved from the bench to the clinic!

There are many hoops to jump through running an FDA (Food and Drug Administration) clinical trial, but we are up to the task. This trial will have 32 participants (16 Parkinson’s disease patients and 16 control subjects). We hope to recruit all participants by the end of 2014/early 2015.

As the NNA endowment grows, we will be able to award pilot project funds both at the bench and in the clinic in disorders of the central nervous system.

In our continued mission to educate the next generation of researchers and clinicians, a special lecture series has been established. The NNA will sponsor national and international speakers on a regular basis along with the annual neuroscience lecture and community support dinner. In 2015, we will honor Robert Gallo, M.D. for his work in HIV and his pioneering work on neurotropic viruses.

Exciting things are happening for the NNA in largest part thanks to community support.

**Calendar**

**Skate-A-Thon**

January 23 - 24, 2015
UNMC Ice Rink
42nd halfway between Dewey Ave. and Emile St.
Noon, Friday, January 23 skating begins;
Closing ceremonies beginning at 11:30 a.m.,
Saturday January 24.

**Nebraska Neuroscience Alliance Lecture and Dinner**

June 4 - 5, 2015
Honoring Robert Gallo, M.D.
Institute of Human Virology
University of Maryland Baltimore School of Medicine and community members.... more information to come Spring 2015.

**For clinical trial recruitment information contact:**
Carol Peterson
Nebraska Medicine
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402.552.2239

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